

Registration, Evaluation, Authorization and Restriction of CHemicals...REACH

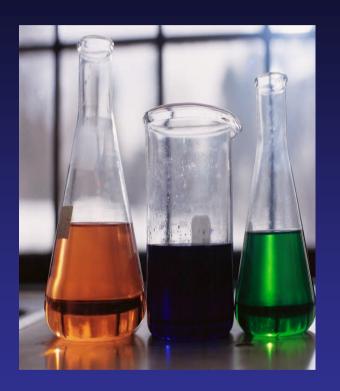


WHAT

- Newer EU legislation that seeks to protect the environment and human health by better regulating chemicals
- Replaces 40 different pieces of chemical legislature already in existence in the EU
- Creates the European Chemicals Agency (ECHA) in Helsinki



- Adopted December 18, 2006
- Became Effective June 1, 2007
- Pre-registration will take place from June 1, 2008 –
 December 1, 2008



EU-based manufacturers, importers and companies using chemicals to be responsible for assessing and managing the effect of chemicals to health and the environment

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- An EU "regulation", meaning it is immediately applicable and needs no transposition into national legislation
- Regulated community can take advantage of gradual introduction of the obligations through to 2018 (not automatic, though)
- Based on the "Precautionary Principle"
- Puts all responsibility of demonstrating the safety of chemical substances on industry, not government. Reversing burden of proof
- Replaces most of the current EU directives and national laws on chemicals



Major impact on international commerce

REACH Applies to the EU



 27 Member States of the European Union are:

Austria Latvia
Belgium Lithuania
Bulgaria Luxembourg

Cyprus Malta

Czech Republic The Netherlands

Denmark Poland
Estonia Portugal
Finland Romania
France Slovakia
Germany Slovenia
Greece Spain
Hungary Sweden

Ireland United Kingdom

Italy



- Norway, Iceland and Liechtenstein:
 - considered WITHIN the EU for REACH
- Switzerland is OUTSIDE the EU

REACH Objectives



- Improve the protection of human health and environment
- Fill regulatory gaps
- Ensure the risks associated with chemicals are measured and understood
- Enhance the competitiveness of the EU chemical industry
- Highly hazardous materials (Substances of Very High Concern, or SVHCs) are properly controlled and that these substances are eventually substituted where economically and technically feasible

REACH is an EU law, but it has a global impact

EU and Chemicals?



The EU is a major producer:

- EU produces 29% of the world's chemicals - largest chemical industry in the world
- A major market: Currently 27 countries, around 497 million people

(the US population is 303 million)

The EU is setting global standards on the environment



The production and use of chemicals is controlled at the EU level, not within individual Member States





All substances... on their own;

or contained in preparations;

(mixture of at least two chemical substances *without* the formation of new substances)

or contained in articles

(All "ingredients", raw materials, consumables, components, alloys and their constituents)







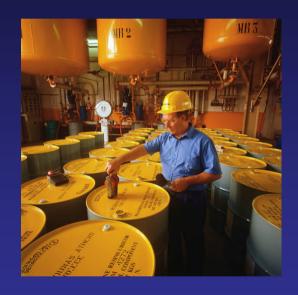
REACH touches all our businesses

ALL Substances are to be Registered...



Compulsory registration of all substances:

- Imported into and/or manufactured in the EU
- In quantities exceeding one tonne per year
- Per legal entity
- Intended to be released from an article, imported into and/or manufactured in the EU
 - Unless the substance has already been registered for that use by its supplier



All substances above 1 tonne per legal entity have to be registered

Definition of an ARTICLE



• <u>Article</u> - object which during production is given a specific <u>shape</u>, <u>surface or design</u> which determines its function to a greater degree than its chemical composition (*Important definition*)

The <u>shape</u>, <u>surface or design</u> is more important than the substances it is made of.





Intentional Release



- Substances in ARTICLES when the substance is INTENDED TO BE RELEASED during normal and reasonably foreseeable circumstances:
 - The INTENTION is important
 - The key test is whether the secondary function of the article is to release a substance. (Example: a scented candle, dye in clothing)
- The EU published guidance on articles RIP 3.8 on May 28, 2008

NOT an intended release....

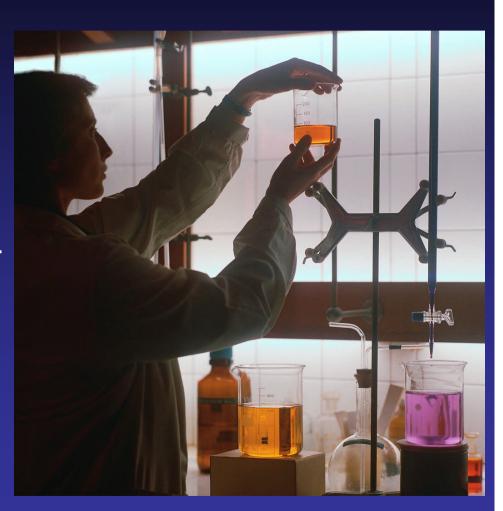
Welding fume, Wearing parts, Combustion products

...Just an INEVITABLE release!

The Registration in REACH



- This will MAINLY be chemical/metal manufacturers and importers
- Pre-register from June 1 –
 December 1, 2008 to benefit
 from a potential 11 year phase in of registration
- Manufacturers and importers will need information from Downstream Users



The Evaluation in REACH



ECHA, with support from Member State authorities, will review the registration dossiers for completeness, accuracy, and compliance with the regulatory requirements



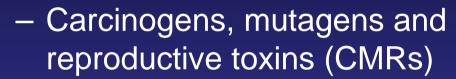


The Authorization in REACH



SVHC

Substances of Very High Concern:



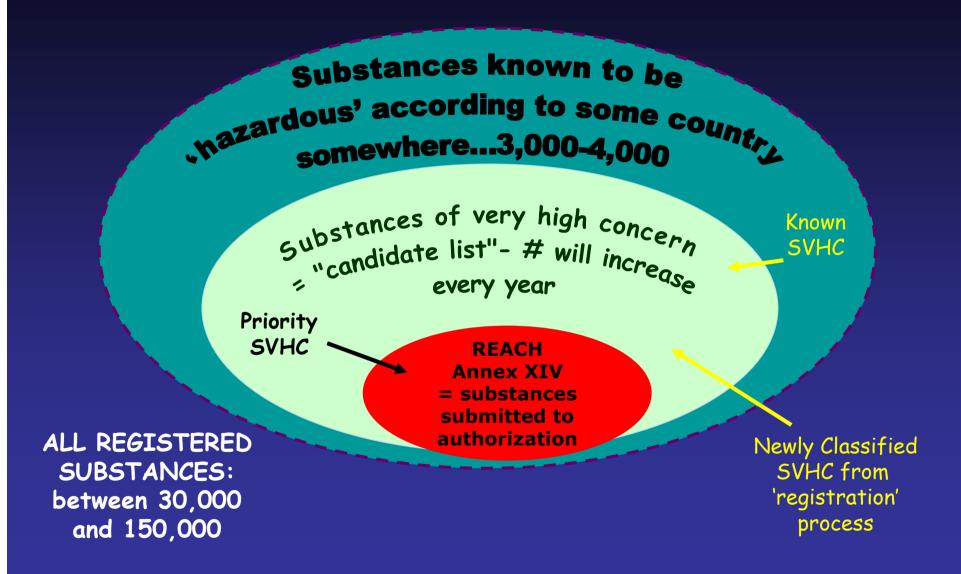




- Persistent, Biocumulative and Toxic (PBT)
- Very persistent and very bioaccumulative (vPvB)
- Substances of equivalent concern (endocrine disruptors)

Substances of Very High Concern...SVHC's





16 Possible SVHC's already Submitted for first 'candidate list'



- 1. Anthracene
- 2. 4,4'- Diaminodiphenylmethane
- 3. Dibutyl phthalate
- 4. Cyclododecane
- 5. Cobalt dichloride
- 6. Diarsenic pentaoxide
- 7. Diarsenic trioxide
- 8. Sodium dichromate, dihydrate
- 9. 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)
- 10.Bis (2-ethyl(hexyl)phthalate) (DEHP)
- 11.Hexabromocyclododecane (HBCDD)
- 12. Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)
- 13.Bis(tributyltin)oxide
- 14.Lead hydrogen arsenate
- 15. Triethyl arsenate
- 16.Benzyl butyl phthalate



There will be a "Sunset date" after which manufacturing and use is only allowed when covered by an ECHA authorization

Manufacturers/Importers will need to

- develop a substitute plan and move to alternatives
 when available / reasonable
- Create a 'socio-economic analysis' and substitute as soon as an alternative is available

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 Substances posing an unacceptable risk can be restricted in their manufacture, placement on the market or use

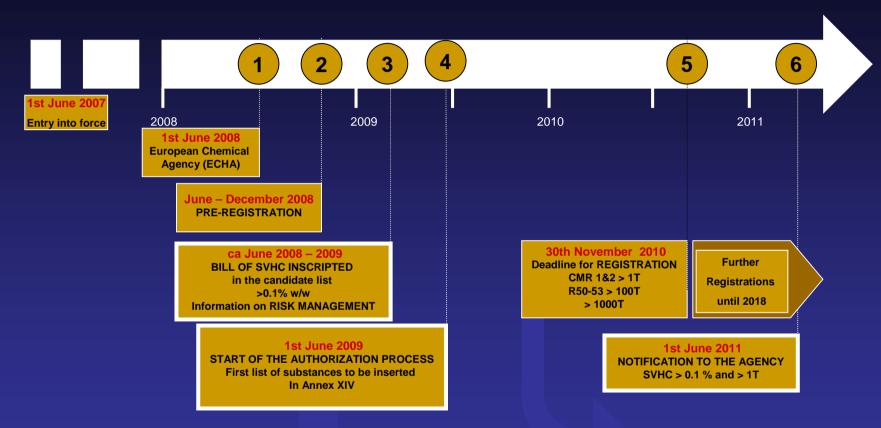


- Restrictions exist in EU law already. Existing restrictions include lead in paint and asbestos
- REACH simply brings this process together into one regulation



REACH Timeline





Applications of substances for which there is no threshold will certainly be highly restricted or prohibited

- Most CMR 1 & 2: CHROMIUM VI, CADMIUM,
- PBT....

NO REGISTRATION
= NO MARKET
SUPPLY CHAIN
DISRUPTION

Enforcement of REACH



Much left to be determined. However:

- Enforcing Regulations are required by December 1, 2008
- EU member state authorities will enforce regulations in accordance with EU Enforcing Regulations
- Companies are expected to take on a role of 'self enforcement' for their supply chains, in order to manage their business risk

Company Impact



- Economic Impact What is at risk?
- Competitive advantage for companies within the EU or for a non-EU company that sells to a company operating in the EU?
- Effect on the supply chain?
 - Reduction of suppliers
 - Increased supplier management costs
- Lost business opportunity & market access in Europe?
- Potential impact to existing deliveries?



And inevitably...





- Some substances may:
 - not be on the market
 (suppliers will choose not to register)
 - be in limited supply
 - be more expensive
 - be phased out
- Some will be withdrawn due to 'authorization'
- The chemical industry is a global marketplace, so the effects will be global

Questions



